

Ex. 5 - Deliberative Process

Current Status of BPPD/Oxitec Interaction: Oxitec has not yet made a PRIA submission to OPP on its Friendly™ mosquito 513A. The table below describes the status of the major data/information development actions currently in play. OPP has met with Oxitec on several occasions over the past several months and communicated by letter detailed explanations of the various pieces of data/information necessary to support both experimental use permit and registration applications. Oxitec has indicated that it intends to submit protocol review PRIA submissions to determine U.S. equivalence of their efficacy data and then, if EPA determines the data is equivalent to U.S. data, submit an application for registration. If EPA determines that the data is not equivalent to U.S. data, Oxitec indicated that it would likely submit an experimental use permit (EUP).

Ex. 5 - Deliberative Process